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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,538	06/27/2003	Caius Rommens	058951-0167	5766

22428 7590 07/05/2007
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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

MAIL DATE DELIVERY MODE

07/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,538

Applicant(s)

ROMMENS ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5,13 and 44-57 is/are pending in the application.
- 4a) Of the above claim(s) 56 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5,13 and 44-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 February 2007 has been entered, as instructed by the RCE filed 17 April 2007.

Applicant's amendments and arguments filed 20 February 2007 have overcome the outstanding indefiniteness and new matter rejections.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Written Description

Claims 3, 5, 13 and 44-55 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-4 of the Final Rejection mailed 20 November 2006.

Enablement

Claims 3, 5, 13 and 44-55 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods of using 25 base pair-long P-DNA borders from plants comprising the consensus sequence of SEQ

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ID NO:47 to transfer foreign DNA to the genome of heterologous plants, does not reasonably provide enablement for claims broadly drawn to any "sequence from a plant" of any length or sequence, or its use to transfer foreign DNA to heterologous plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 5-7 of the Final Rejection mailed 20 November 2006.

Applicant's Arguments

Applicant's arguments on pages 7-18 of the Response filed 20 February 2007, regarding the written description and enablement rejections, have been fully considered but they are not persuasive. Applicant urges that *Lilly* does not require that they recite a particular consensus sequence, given the amendment of the claims to remove "border-like"; the knowledge by the skilled artisan of the physical properties of T-DNA borders; the provision of an adequate number of representative species by Applicant; the failure of other US patents to claim particular consensus sequences when reciting other genetic elements such as polyA signals, CAAT or TATA boxes; the permissibility of some inoperative embodiments as evidenced by *Atlas Powder*; and the inapplicability of *Bayer*, given Applicant's guidance regarding the "structure, e.g., nucleotide sequence, of the border-like sequences" (see, e.g., page 16 of the Response of 20 February 2007, first full paragraph).

The Examiner maintains that the claims remain broadly drawn to any sequence of any length, including 5-100 nt, which genus is much broader than the genus of plant

sequences demonstrated to have "border-like" (or integrative) function. Even though the claims no longer recite "border-like", they are still drawn to the broad genus of any sequence of any length from any plant which somehow functions like a T-DNA border sequence to cause integration of heterologous DNA into the plant genome.

Regarding the knowledge of the physical properties of T-DNA borders, the Examiner notes that the claims are not so limited. Furthermore, T-DNA borders have the physical property of being 25 base pairs long and having a consensus sequence, neither of which are recited in the instant claims.

Regarding the provision of species by Applicant, the Examiner notes that said species all comprise 25 base pair-long sequences with a particular consensus sequence. Furthermore, most of the species have not actually been tested in the instant specification for their ability to effect integration of heterologous DNA, and a substantial portion of those that have been later tested by Applicant failed to function as predicted.

Applicant's arguments re TATA box or T-DNA border recitations in other patents are not persuasive, since these sequences are much smaller than the instantly claimed sequences, and are much better characterized and well-known. Applicant's sequences are a new class of sequences, and theoretically encompass as much as 100 base pairs, while Applicant has characterized only 25 base-pair sequences.

Regarding the permissibility of inoperative embodiments, the Examiner maintains that Applicant has not provided guidance for how to "identify...candidate border-like sequences" which broadly encompass as few as 5 nucleotides or as many as 100

nucleotides, and which have no particular sequence recited at even a single base pair. In *Atlas Powder*, the court deemed that the claims were enabled because the blasting powder involved the use of salts and fuels which were previously-known and well-characterized types of compounds. In the instant situation, however, plant-derived sequences which cause integration of heterologous DNA sequences were previously unknown and uncharacterized. Thus, the court in *Atlas Powder* would not have found that Applicant's claims were enabled.

Regarding *Bayer*, the Examiner maintains that the structure provided by Applicant, namely a 25 base-pair sequence comprising a consensus sequence, is nowhere recited in the claims. Applicant has provided no guidance how to recognize sequences as small as 5 nucleotides or as large as 100 nucleotides, of any sequence at all, which may function to integrate heterologous DNA into a plant genome.

Anticipation

Claim 13 remains rejected under 35 U.S.C. 102(e) as being anticipated by McElroy et al (US 6,750,379 effectively filed 09 March 2000), as stated on pages 7-8 of the Final Rejection mailed 20 November 2006.

Applicant's arguments filed 20 February 2007 have been fully considered but they are not persuasive. Applicant urges that McElroy does not teach the claimed invention, because a single nucleotide found in the genome of the plant taught by McElroy would be identical to a single nucleotide found in a T-DNA border.

However, amended claim 13 does not stipulate that the 5-100 nt portion of the integrative sequence not be identical to a T-DNA border sequence. Instead, the claim

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merely recites that the *entire* plant-derived integrative sequence not be identical to a T-DNA border sequence. The claimed 5 nt-long sequence is indistinguishable from any random sequence found in the genome of the plant taught by McElroy, or found in the vector taught by McElroy to transform the plant, including linker sequences. Applicant's argument that McElroy does not teach the claimed invention, because a single nucleotide found in the genome of the plant taught by McElroy would be identical to a single nucleotide found in a T-DNA border, is not persuasive. Using the same logic, a single nucleotide found in the claimed non-T-DNA plant integrative sequence would also contain a single nucleotide which could be found in a T-DNA border, thus rendering the claim inoperative.

Conclusion

Claims 3, 5 and 44-55 remain free of the prior art, as stated previously.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 23, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read 'D. Fox', is written below the printed name and title.